DOCKET # X06-UWY-CV-14-6025333-S : SUPERIOR COURT

•

ROBIN SHERWOOD, ET AL : J.D. OF WATERBURY

:

v. : COMPLEX LITIGATION DOCKET

. OCTODED 15 401

STAMFORD HEALTH SYSTEM, ET AL : OCTOBER 15, 2015

THIRD PARTY DEFENDANT ETHICON, INC.'S ANSWER AND SPECIAL DEFENSES

Third Party Defendant Ethicon, Inc. hereby answers the Third Party Complaint of Stamford Health System, Inc. d/b/a Stamford Hospital, dated August 13, 2015 ("Third Party Complaint") as follows. Any allegation not specifically admitted is deemed denied.

- 1. Ethicon, Inc. lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Third Party Complaint and, therefore, denies the allegations.
- 2. Ethicon, Inc. states that the plaintiffs' complaint speaks for itself. Ethicon, Inc. denies the remaining allegations in paragraph 2 of the Third Party Complaint.
- 3. Ethicon, Inc. admits that Johnson & Johnson ("J&J") is a business corporation organized under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza in New Brunswick, New Jersey and refers to J&J's website for its contents. Ethicon, Inc. further admits that Ethicon, Inc. designed, manufactured, and sold

certain pelvic floor repair products. Ethicon, Inc. denies the remaining allegations in paragraph 3 of the Third Party Complaint.

- 4. Ethicon, Inc. admits that it is a business corporation organized under the laws of the State of New Jersey with its principal place of business at Route 22 West, Somerville, New Jersey 08876 and that it is a wholly owned subsidiary of J&J. Ethicon, Inc. denies the remaining allegations in paragraph 4 of the Third Party Complaint.
- 5. Ethicon, Inc. admits that Ethicon LLC is a limited liability company organized under the laws of the State of Delaware and that it has manufactured certain mesh products for uses consistent with their packaging and labeling. Ethicon, Inc. denies the remaining allegations contained in paragraph 5 of the Third Party Complaint.
- 6. Ethicon, Inc. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 6 of the Third Party Complaint and, therefore, denies those allegations.
- 7. Ethicon, Inc. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 7 of the Third Party Complaint and, therefore, denies those allegations.

- 8. Ethicon, Inc. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 8 of the Third Party Complaint and, therefore, denies those allegations.
- 9. Ethicon, Inc. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 9 of the Third Party Complaint and, therefore, denies those allegations.

Count One: Product Liability

- 10. Paragraph 10 contains no allegations to which a response is required. To the extent paragraph 10 is deemed to contain allegations against Ethicon, Inc., Ethicon, Inc. denies the allegations.
- 11. The allegations of Paragraph 11 are not directed to Ethicon, Inc. and therefore do not require a response. To the extent a response is required, Ethicon, Inc. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 11 and, therefore, denies the allegations.
- 12. Ethicon, Inc. admits only that it manufactured certain pelvic mesh products for uses consistent with their packaging and labeling. The remaining allegations of Paragraph 12 are not directed to Ethicon, Inc. and therefore do not require a response. To the extent a

response is required, Ethicon, Inc. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 12 and, therefore, denies the allegations.

- 13. Ethicon, Inc. states that plaintiffs' complaint speaks for itself. To the extent a response is required, Ethicon, Inc. denies the allegations contained in Paragraph 13 of the Third Party Complaint.
- 14. Ethicon, Inc. states that plaintiffs' complaint speaks for itself. To the extent a response is required, Ethicon, Inc. denies the allegations contained in Paragraph 14 of the Third Party Complaint.
- 15. Ethicon, Inc. states that plaintiffs' complaint speaks for itself. Ethicon, Inc. admits that it designed, manufactured and sold certain pelvic mesh products for uses consistent with their packaging and labeling and denies the remaining allegations in paragraph 15 of the Third Party Complaint. Ethicon, Inc. further states that J&J is a holding company and does not develop, patent, market, or sell any product.
- 16. Ethicon, Inc. states that plaintiffs' complaint speaks for itself. Ethicon, Inc. admits that it designed, manufactured and sold certain pelvic mesh products for uses consistent with their packaging and labeling and denies the remaining allegations in paragraph

16 of the Third Party Complaint. Ethicon, Inc. further states that J&J is a holding company and does not market, distribute, manufacture, package, repackage, sell, resell, install, design, or prepare for use any product.

- 17. Ethicon, Inc. states that plaintiffs' complaint speaks for itself. To the extent a response is required, Ethicon, Inc. admits that it designed, manufactured and sold certain pelvic mesh products for uses consistent with their packaging and labeling. Ethicon, Inc. further states that J&J is a holding company and does not market, distribute, manufacture, package, repackage, sell, resell, install, design, or prepare for use any product. Ethicon, Inc. denies the remaining allegations in paragraph 17 of the Third Party Complaint.
- 18. Ethicon, Inc. states that plaintiffs' complaint speaks for itself. To the extent a response is required, Ethicon, Inc. admits that it designed, manufactured and sold certain pelvic mesh products for uses consistent with their packaging and labeling and denies the remaining allegations in paragraph 18 of the Third Party Complaint.
- 19. Ethicon, Inc. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 19 of the Third Party Complaint and, therefore, denies those allegations.

- Ethicon, Inc. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 20 of the Third Party Complaint and, therefore, denies those allegations.
- 21. Ethicon, Inc. states that plaintiffs' complaint speaks for itself. To the extent a response is required, Ethicon, Inc. denies the allegations contained in the Paragraph 21 of the Third Party Complaint.
- 22. Ethicon, Inc. denies the allegations in paragraph 22 of the Third Party Complaint, including all sub-parts thereof.
- 23. Ethicon, Inc. denies the allegations in paragraph 23 of the Third Party Complaint.

RESPONSE TO PRAYER FOR RELIEF

In response to the paragraph beginning "WHEREFORE," in Third Party Plaintiff's Prayer for Relief, Ethicon, Inc. denies that Plaintiffs and Third Party Plaintiff are entitled to any recovery, including subparts (1) through (3), or any form of relief whatsoever, demands judgment in its favor and against Third Party Plaintiff on all causes of action, demands a trial by jury, and such other and further relief as this Court deems appropriate.

SPECIAL DEFENSES

FIRST DEFENSE

The Third Party Complaint and the underlying complaint fail to state a cause of action upon which relief can be granted.

SECOND DEFENSE

The Third Party Complaint and the underlying complaint fail to state a cause of action upon which relief can be granted due to lack of adequate product identification.

THIRD DEFENSE

Third Party Plaintiff's and the Plaintiffs' claims are barred for lack of subject matter jurisdiction.

FOURTH DEFENSE

Third Party Plaintiff's and the Plaintiffs' claims are barred for lack of personal jurisdiction.

FIFTH DEFENSE

The Third Party Complaint must be dismissed because Third Party Plaintiff provided insufficient process.

SIXTH DEFENSE

The Third Party Complaint must be dismissed because Third Party Plaintiff provided insufficient service of process.

SEVENTH DEFENSE

Third Party Plaintiff may be barred from bringing some or all of the claims alleged in the Third Party Complaint because Third Party Plaintiff may lack standing and/or capacity to bring such claims.

EIGHTH DEFENSE

Third Party Plaintiff may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

NINTH DEFENSE

Certain of Third Party Plaintiff's and Plaintiffs' claims and remedies and the defenses thereto are governed by the laws of a foreign jurisdiction or the laws of the United States.

TENTH DEFENSE

Third Party Plaintiff's alleged causes of action have been improperly joined under the applicable Rules of Civil Procedure and the laws of the applicable state.

ELEVENTH DEFENSE

The improper joinder of Third Party Plaintiff's alleged causes of action violate the procedural and substantive due process rights of Ethicon under the Constitutions of the United States of America and the applicable state.

TWELFTH DEFENSE

Ethicon, Inc. is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in this State and any other state whose law is deemed to apply in this case.

THIRTEENTH DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are barred by the doctrine of federal preemption, as established by statute, including the preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and by state and federal case law, and are barred by the Supremacy Clause of the United States Constitution, because the products at issue are regulated by the U.S. Food and Drug Administration ("FDA") under the Medical Device Amendments, 21 U.S.C. § 360k, et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulation.

FOURTEENTH DEFENSE

At all relevant times, Ethicon, Inc. was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360k, et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulations, and Third Party Plaintiff's claims are accordingly barred.

FIFTEENTH DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are expressly and/or impliedly preempted by federal law, including but not limited to, the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. See 21 U.S.C. § 301 et seq.; see also Fed. Reg. 3922 (Jan. 24, 2006).

SIXTEENTH DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are barred because Ethicon, Inc. complied with all applicable state and federal statutes regarding the products at issue including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that Third Party Plaintiff's and Plaintiffs' claims are not barred, Ethicon, Inc. is entitled to a presumption that the products at

issue are free from any defect or defective condition as the plans or design for the products at issue or the methods and techniques of manufacturing, inspecting, and testing the products at issue were in conformity with government standards established for the industry that were in existence at the time the plans or designs for the products at issue or the methods and techniques of manufacturing, inspecting, and testing the products at issue were adopted.

SEVENTEENTH DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 et seq., and regulations promulgated thereunder.

EIGHTEENTH DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because Ethicon, Inc. complied with all applicable statutes and with the requirements and regulations of the FDA.

NINETEENTH DEFENSE

Any claims by Third Party Plaintiff or Plaintiff relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Ethicon, Inc. to petition the government.

TWENTIETH DEFENSE

Third Party Plaintiff's and Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for medical devices.

TWENTY-FIRST DEFENSE

Third Party Plaintiff and Plaintiffs cannot state a claim with regard to warnings and labeling for medical devices because the remedy sought is subject to the exclusive regulation of FDA.

TWENTY-SECOND DEFENSE

All claims for punitive damages are barred because the products at issue were manufactured and labeled in accordance with the terms of FDA's clearance of the products at issue.

TWENTY-THIRD DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are barred in whole or in part by Third Party Plaintiff's and Plaintiffs' failure to assert a safer design for any of the products at issue.

TWENTY-FOURTH DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are barred in whole or in part because the products at issue provided a benefit to users of such products and greatly outweighed any risk created by using such products, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

TWENTY-FIFTH DEFENSE

Ethicon, Inc. made no express or implied representations or warranties of any kind to Plaintiff or Third Party Plaintiff, nor did Plaintiff or Third Party Plaintiff rely on any representations or warranties made by Ethicon, Inc. to others. To the extent Plaintiff or Third Party Plaintiff relied upon any representations or warranties, such reliance was unjustified.

TWENTY-SIXTH DEFENSE

Any express or implied warranties alleged to have been made by Ethicon, Inc. were disclaimed.

TWENTY-SEVENTH DEFENSE

Ethicon, Inc. did not make nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that Third Party Plaintiff or Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between Third Party Plaintiff and Plaintiff and Ethicon, Inc. and/or by Third Party Plaintiff's and Plaintiffs' failure to give Ethicon, Inc. timely notice of the alleged breach of warranty and an opportunity to cure. Ethicon, Inc. further specifically pleads as to any breach of warranty claim all affirmative defenses available to Ethicon, Inc. under the Uniform Commercial Code, as enacted in the State of Connecticut or any other state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

TWENTY-EIGHTH DEFENSE

Ethicon, Inc. specifically pleads as to any claim alleging a violation of consumer protection laws, all affirmative defenses available to Ethicon, Inc. under the rules and statutes

of any state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

TWENTY-NINTH DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, were not foreseeable to Ethicon, Inc. given the state of scientific knowledge and state of the art at the time of the alleged injuries. At all times relevant, the products at issue conformed to state-of-the-art specifications and state-of-scientific knowledge for such products at that time, as well as all applicable statutes and regulations, including those of FDA.

THIRTIETH DEFENSE

Third Party Plaintiff and Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the products at issue in this case and thus the "last clear chance" and assumption of the risk doctrines bar in whole or in part the damages that Third Party Plaintiff and Plaintiffs seek to recover herein.

THIRTY-FIRST DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are barred, in whole or in part, because Ethicon, Inc. acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of its products.

THIRTY-SECOND DEFENSE

At all relevant times herein, the products in question were manufactured and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

THIRTY-THIRD DEFENSE

Third Party Plaintiff's and Plaintiffs' inadequate warning claims are barred because the alleged risk of which claim is open, obvious, and/or a matter of common knowledge.

THIRTY-FOURTH DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are barred in whole or in part because the products at issue were consistent with and/or exceeded consumer expectations.

THIRTY-FIFTH DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are barred in whole or in part because the products at issue were at all times properly prepared, packaged, and distributed, and were not defective or unreasonably dangerous.

THIRTY-SIXTH DEFENSE

Adequate and complete warnings and instructions were provided with the products at issue. The products at issue were neither defective nor unreasonably dangerous when used according to their Instructions for Use.

THIRTY-SEVENTH DEFENSE

At all relevant times, the warnings and instructions accompanying the products at issue were governed by and conformed to applicable federal statutes, rules and regulations; therefore, warnings and instructions relating to the products were presumptively adequate.

THIRTY-EIGHTH DEFENSE

Third Party Plaintiff's and Plaintiffs' causes of action are barred by the learned intermediary doctrine.

THIRTY-NINTH DEFENSE

Ethicon, Inc. is not liable to Third Party Plaintiff or the Plaintiffs because the end users of the products at issue, Plaintiff's physician(s), were sophisticated users of the products.

FORTIETH DEFENSE

Ethicon, Inc. states that the sole proximate cause of the injuries and/or damages alleged by Plaintiff and Third Party Plaintiff was the actions, omissions, or negligence of a person or persons, other than Ethicon, Inc., for whose actions, omissions, or negligence Ethicon, Inc. is in no way liable. Third Party Plaintiff is not, therefore, entitled to recover from Ethicon in this action. As to Third Party Plaintiff or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of Plaintiff or Third Party Plaintiff, if any, Ethicon, Inc. expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or comparative negligence, as well as the provisions of any applicable comparative fault and/or comparative negligence and/or contributory negligence statute, law or policy of the applicable states.

FORTY-FIRST DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, may have been caused, in whole or in part, by Third Party Plaintiff's and Plaintiffs' own fault, which bars or proportionately reduces Ethicon Inc.'s liability, if any, for Third Party Plaintiff's and Plaintiffs' alleged damages.

FORTY-SECOND DEFENSE

Plaintiff voluntarily and unreasonably chose to encounter known dangers.

FORTY-THIRD DEFENSE

The liability of Ethicon, Inc., if any, for Third Party Plaintiff's and Plaintiffs' non-economic loss must be apportioned in accordance with the provisions of the law of the applicable states.

FORTY-FOURTH DEFENSE

In the event Ethicon, Inc. is held liable to Third Party Plaintiff, which liability is expressly denied, and any other co-defendants are also held liable, Ethicon is entitled to a percentage contribution of the total liability from said co-defendants or responsible parties in accordance with principles of equitable indemnity and comparative contribution and pursuant to any applicable contribution or apportionment statute, law or policy of the applicable states.

FORTY-FIFTH DEFENSE

There is no causal relationship between Ethicon Inc.'s conduct and the injuries and damages alleged by Plaintiffs and Third Party Plaintiff.

FORTY-SIXTH DEFENSE

At all times mentioned herein, Third Party Plaintiff was negligent, careless and at fault and conducted itself so as to contribute substantially to its alleged injuries, losses, and damages. Said negligence, carelessness and fault of Third Party Plaintiff bars in whole or in part the damages which Third Party Plaintiff seeks to recover herein.

FORTY-SEVENTH DEFENSE

Plaintiff's and Third Party Plaintiff's alleged injuries, losses, or damages attributable to the use of the products at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said products.

FORTY-EIGHTH DEFENSE

Plaintiff's and Third Party Plaintiff's alleged injuries, losses, or damages attributable to the use of the products at issue in this case, if any, were not legally caused by the products at issue, but instead were legally caused by intervening and superseding causes or circumstances.

FORTY-NINTH DEFENSE

Plaintiff's and Third Party Plaintiff's alleged injuries, losses, or damages attributable to the products at issue in this case, if any, were caused by the acts or omissions of third parties for which Ethicon, Inc. has no legal responsibility.

FIFTIETH DEFENSE

Ethicon, Inc. expressly denies any third party engaging in the acts alleged by Third Party Plaintiff and Plaintiffs was acting as Ethicon Inc.'s agent or servant, at the instruction of Ethicon, Inc., or within its control. Therefore, Third Party Plaintiff's and Plaintiffs' claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

FIFTY-FIRST DEFENSE

Third Party Plaintiff's and Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic or idiopathic reaction to the products at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Ethicon.

FIFTY-SECOND DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are or may be barred by their failure to comply with conditions precedent to their right to recover.

FIFTY-THIRD DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are barred, in whole or in part, by the doctrine of avoidable consequences.

FIFTY-FOURTH DEFENSE

The claims of Third Party Plaintiff and Plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence and the failure to preserve evidence necessary to the determination of the claim.

FIFTY-FIFTH DEFENSE

Third Party Plaintiff's and Plaintiffs' claims against Ethicon, Inc. are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel. Additionally, if Third Party Plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Third Party Complaint or files for bankruptcy at some point in the future, the claims of Third Party Plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the

bankruptcy trustee rather than Third Party Plaintiff, or, if not disclosed by Third Party Plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

FIFTY-SIXTH DEFENSE

Some or all of Third Party Plaintiff's and Plaintiffs' claims may be barred by the statutes of limitations, prescription, and/or statues of repose of the applicable states.

FIFTY-SEVENTH DEFENSE

To the extent Third Party Plaintiff's and Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by <u>Buckman Co.</u> v. Plaintiff's Legal Committee, 531 U.S. 341 (2001).

FIFTY-EIGHTH DEFENSE

Third Party Plaintiff's and Plaintiffs' alleged damages, if any, are barred in whole or in part by failure to mitigate such damages.

FIFTY-NINTH DEFENSE

The sale, labeling and marketing of the products at issue in this litigation is not, and was not, likely to mislead or deceive the public.

SIXTIETH DEFENSE

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

SIXTY-FIRST DEFENSE

Plaintiff's and Third Party Plaintiff's claims are barred in whole or in part under Section 402A, comments j and k of the Restatement (Second) of Torts.

SIXTY-SECOND DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are barred, in whole or in part, to the extent they have released, settled, entered into an accord and satisfaction, or otherwise compromised its claims by any means.

SIXTY-THIRD DEFENSE

Any recovery by Third Party Plaintiff must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

SIXTY-FOURTH DEFENSE

Third Party Plaintiff's Complaint and thee underlying complaint fail to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-

judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement or restitution.

SIXTY-FIFTH DEFENSE

The Third Party Complaint and the underlying complaint fail to state facts sufficient to entitle Third Party Plaintiff or Plaintiffs' to an award of punitive damages.

SIXTY-SIXTH DEFENSE

No act or omission of Ethicon, Inc. was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

SIXTY-SEVENTH DEFENSE

Third Party Plaintiff's claims based on Plaintiff's claims for pain and suffering are barred because they violate Ethicon, Inc.'s rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and the applicable states.

SIXTY-EIGHTH DEFENSE

The imposition of punitive or exemplary damages would violate Ethicon Inc.'s constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent

or correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States. To the extent that punitive damages awarded to any Plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution as amended; (3) imposed where state law is

impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Ethicon Inc.'s conduct within the State where each Plaintiff resides, or in any other way subject Ethicon, Inc. to impermissible multiple punishment for the same alleged wrong.

SIXTY-NINTH DEFENSE

Ethicon, Inc. specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the applicable states under the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

SEVENTIETH DEFENSE

With respect to Plaintiff's demand for punitive damages, Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under <u>BMW of North America, Inc. v.</u>

<u>Gore</u>, 517 U.S. 559 (1996); <u>Cooper Industries</u>, <u>Inc. v. Leatherman Tool Group</u>, <u>Inc.</u>, 532 U.S. 424 (2001); <u>State Farm Mutual Auto Insurance Company</u>. <u>v. Campbell</u>, 538 U.S. 408 (2003); Philip Morris USA v. Williams, 549 U.S. 346 (2007), and their progeny, as applied

by the federal courts of appeals, together with all such standards applicable under any other state's law.

SEVENTY-FIRST DEFENSE

Ethicon, Inc. asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of the applicable states.

SEVENTY-SECOND DEFENSE

Ethicon, Inc. specifically pleads as to all claims for punitive damages, all affirmative defenses available to Ethicon, Inc. under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

SEVENTY-THIRD DEFENSE

Ethicon, Inc. specifically pleads as to all strict liability claims, all affirmative defenses available to Ethicon, Inc. under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

SEVENTY-FOURTH DEFENSE

Ethicon, Inc. specifically pleads as to all negligence claims, including separate negligence claims under Connecticut law, all affirmative defenses available to Ethicon, Inc. under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

SEVENTY-FIFTH DEFENSE

Ethicon, Inc. hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant or by Third Party Plaintiff in this lawsuit.

SEVENTY-SIXTH DEFENSE

Ethicon, Inc. reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

SEVENTY-SEVENTH DEFENSE

Third Party Plaintiff's and Plaintiffs' claims are barred in whole or in part because the products were altered or modified within the meaning of General Statutes § 52-572p.

WHEREFORE, Ethicon denies that it is liable to Third Party Plaintiff or Plaintiffs for damages or any other relief requested in the "Prayer for Relief" section of the Third Party Complaint, including the paragraph beginning "WHEREFORE" and subparagraphs (1)-(3) thereto; Ethicon, Inc. prays that:

- (1) Third Party Plaintiff take nothing by reason of its Third Party Complaint;
- (2) the Third Party Complaint be dismissed in its entirety and that a Judgment against Third Party Plaintiff and in favor of Ethicon, Inc. be entered;
 - (3) Ethicon, Inc. be awarded its costs and expenses; and
- (4) this Court award Ethicon, Inc. such other and further relief as this Court may deem just and proper.

Respectfully submitted,

THIRD PARTY DEFENDANT, ETHICON, INC.

By: /s/ Christopher R. Drury

Robert R. Simpson Christopher R. Drury Shipman & Goodwin LLP One Constitution Plaza Hartford, CT 06103 Juris No.: 57385

Tel: (860) 251-5000 Fax: (860) 251-5216 rsimpson@goodwin.com cdrury@goodwin.com

Its Attorneys

CERTIFICATION OF SERVICE

The undersigned hereby certifies that on October 15, 2015, a copy of the foregoing THIRD PARTY DEFENDANT ETHICON, INC.'S ANSWER AND SPECIAL DEFENSES was sent via email to the following counsel of record:

Brenden P. Leydon, Esq. Jaqueline E. Fusco, Esq. Toober, Wool & Leydon, I.

Tooher, Wocl & Leydon, LLC

80 Fourth Street Stamford, CT 06905 Tel.: (203) 517-0456 Fax: (203) 324-1407

E-mail: BLeydon@tooherwocl.com

ifusco@tooherwocl.com

Attorneys for Plaintiffs

Eric J. Stockman, Esq. Simon I. Allentuch, Esq.

Neubert, Pepe & Monteith, P.C. 195 Church Street, 13th Floor New Haven, CT 06510

Tel.: (203) 821-2000 Fax: (203) 821-2009

E-mail: estockman@npmlaw.com SAllentuch@npmlaw.com sbraun@npmlaw.com

Attorneys for Defendant Stamford Health System Inc. d/b/a Stamford Hospital

Thomas P. O'Dea, Jr., Esq.
Diserio Martin O'Connor & Castiglioni LLP
One Atlantic Street

Stamford, CT 06901 Tel.: (203) 358-0800 Fax: (203) 348-2321

E-mail: todea@dmoc.com

Attorneys for Third Party Defendants American Medical Systems, Inc. and American Medical Systems Holding, Inc.

/s/ Christopher R. Drury
Christopher R. Drury